

RF QIMT  
RF QAS

“RF-Data provides physicians with extra help in the risk assessment of cardiovascular disease (CVD) and target organ damage (TOD). Accuracy, ease of use and reliability are the core of this innovative technological tool”

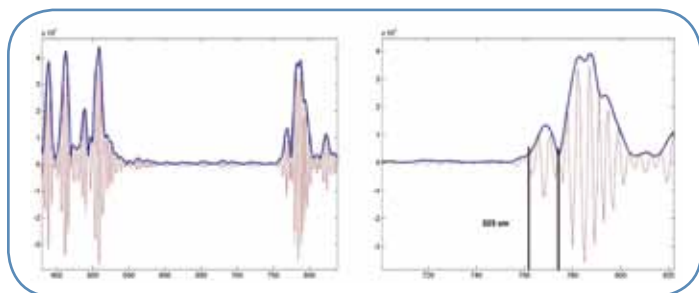
Dr. ing. P.J. Brands, Advanced Projects, Esaote, Maastricht, The Netherlands

Innovations in ultrasound technology as developed by Esaote allows for measuring intima media vessel wall thickness (IMT) and arterial stiffness automatically and accurately by means of ultrasound radio frequency data (RFdata) technology. The Esaote ultrasound systems combine advantages of B-mode imaging (visual morphology) with integrated RF-data technology for automatic assessment of blood vessel wall properties and most importantly with inherent measurement quality feedback.

Major clinical studies have shown that intima-media wall thickness (IMT) and stiffness of the carotid artery is associated with the risk of cardiovascular disease (CVD). The most important changes in arteries described in these studies in relation to CVD are stiffness of the elastic vessels and thickening of their walls correlations that remain significant after correcting for age.

### Why RF-data technology?

Ultrasonic waves have an intimate and strong interaction with propagating media, only the radio frequency (RF) signal received preserves 100% of the informative content collected. A B-Mode ultrasound image is a non-linear gray-scale representation of the RF signals received. The non-linear character of the B-mode image processing necessary for optimal image quality makes the B-mode image unsuitable for measuring blood vessel wall properties. Therefore, by obtaining RF-data technology for the measurement of blood vessel wall properties Esaote uses 100% of the available information in the data received, solving the traditional compromise between image quality and measurement quality. The potentiality of the available information in the RF-data can be explored by advanced signal processing.

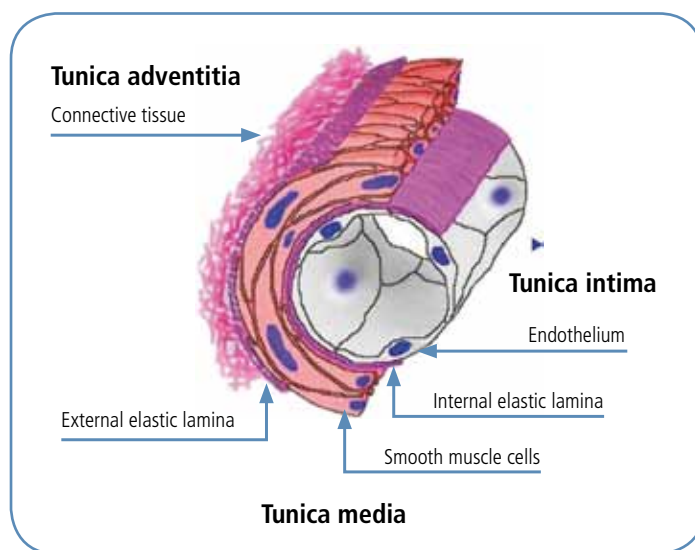


The Radio Frequency signal (red) directly related to the ultrasound wave received with amplitude information (blue).

### Assessment of Blood Vessel Wall Properties by means of ultrasound

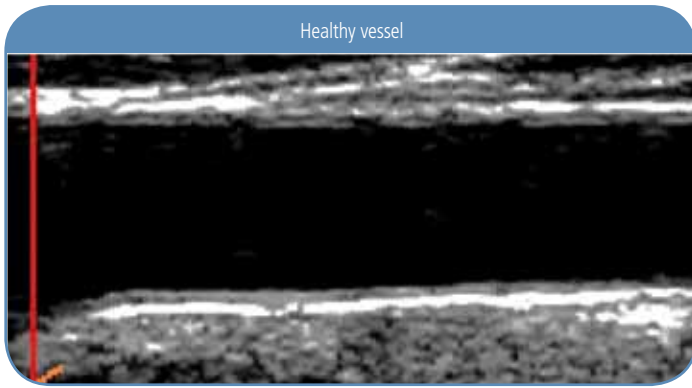
Cardio Vascular Disease (CVD) is the most common cause of death in adults worldwide. CVD is not only a major threat to individuals and their “quality” and “durability” of life, but is also a major economic burden. Early detection and monitoring of progression can provide the opportunity for early medication therapy rather than surgery at a later and more critical phase. Early indications of CVD are:

- Thickening of the blood vessel wall
- Stiffening of the blood vessel wall
- High blood pressure
- High-level of cholesterol

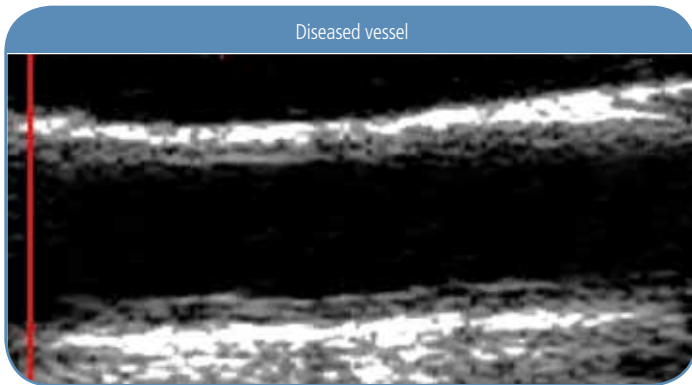


### Thickening of the blood vessel wall

Clinical studies have shown that an increased vessel wall thickness (IMT) was associated with an increased risk of incident myocardial infarction. Therefore, IMT has been used as an important atherosclerosis surrogate in clinical practice and in many clinical studies.



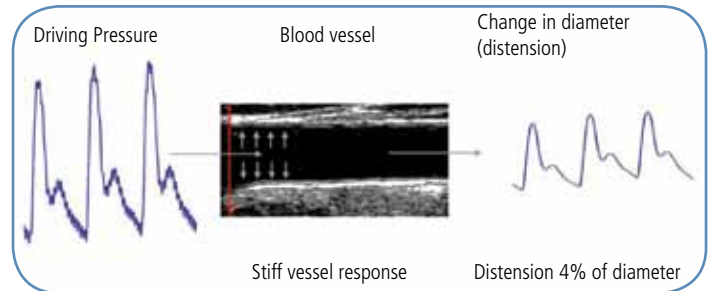
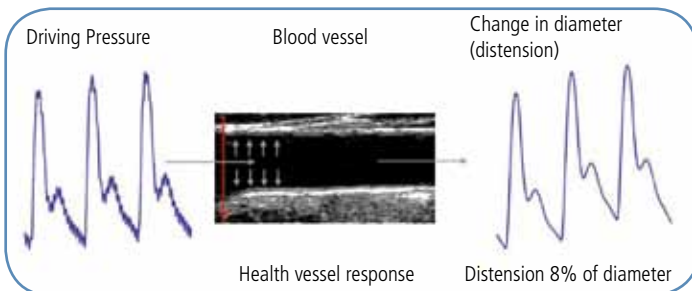
Healthy vessel



Diseased vessel

### Stiffening of the blood vessel wall

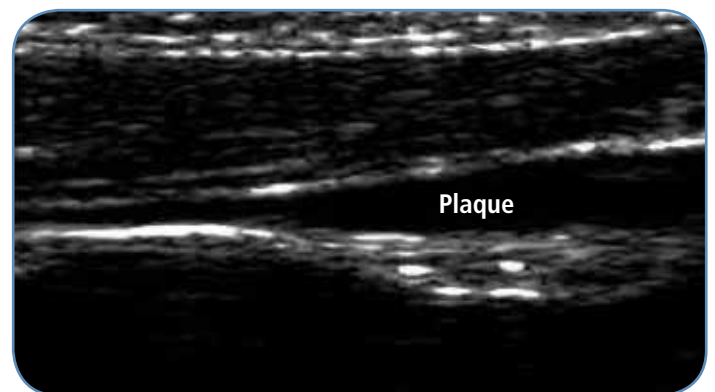
Stiffening of the blood vessel wall is the result of a long, but steady process and is accelerated by life style (food, smoking, lack of exercise and increased weight). In its final phase people are confronted with the disastrous consequences, e.g. high systolic blood pressure, myocardial infarction and stroke.



The progression of CVD will result in plaque formation with consequent reduction in blood flow possibly leading to cardiovascular problems including heart failure, myocardial infarction and stroke. Heart failure can be the consequence of a diseased and stiff arterial tree, transferring too much load on the heart itself and yielding consequent remodeling of the ventricles. Myocardial infarction is usually related to myocardial ischemia because of reduced blood flow. Stroke is mostly caused by plaque rupture that generates emboli reaching and blocking the cerebral circulation.

CVD is the result of a long, but steady process and is accelerated by life style (food, smoking, lack of exercise and increased weight). In its final phase people are confronted with the disastrous consequences.

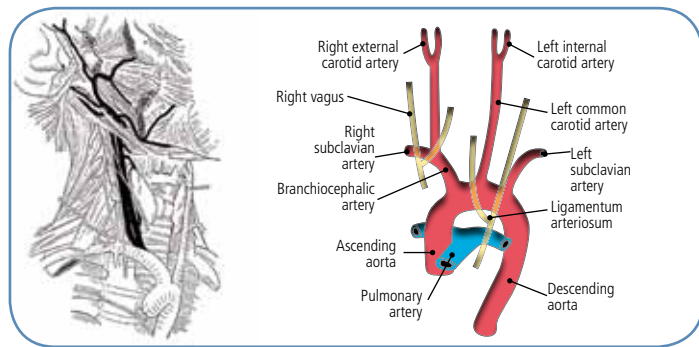
Today no direct feedback can be provided to subjects about the quality of their vascular condition, with the consequence that no early treatment or early follow-up is initiated to prevent further degradation of the vascular condition and to delay the moment that the disease causes serious troubles.



## RFQAS and RFQIMT Technologies

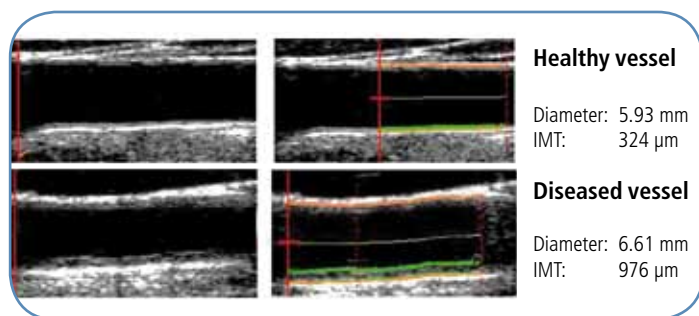
Quality Arterial Stiffness (RFQAS) and Quality Intima media Thickness (RFQIMT) are based on the Esaote RF-datatechnology for the accurate assessment of arterial stiffness and vessel wall thickness.

They are the first step to early detection and early follow-up of CVD, preventing further degradation of the vascular condition and to delay the moment that the disease causes serious troubles. The RFQAS and RFQIMT measurements are taken at the Common Carotid Artery, which represents a critical point in the vascular system.



## Quality intima media thickness (RFQIMT)

RFQIMT targets the measurement of the blood vessel wall thickness of a subject in a selected area of investigation. The ease of use combined with the real time quality feedback helps the operator to achieve accurate and reproducible results. The measures (even taken at different examination times) can be reported on a normalised graph represented as plot indicators to assist physicians in their diagnostic and therapeutically procedures.



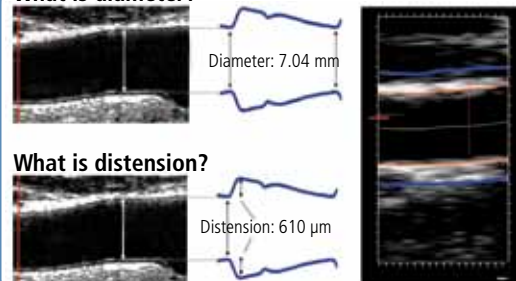
For a properly carry out of the IMT measurement it is recommended to follow the Mannheim protocol which describes very clearly the procedure. The software of the system supports the Mannheim protocol in the measurement process and in the reporting structure. During the scanning of the carotid artery the doctor gets real-time feedback on measurement quality via quality indicators overlaid on the ultrasound image at the position of the vessel wall (orange lines) and the far wall intima layer (green line). This real time feedback gives the doctor the possibility to optimize his probe position to have the best perpendicular position of the scan plane in respect to the far wall of the common carotid artery.

## Quality Arterial Stiffness (RFQAS)

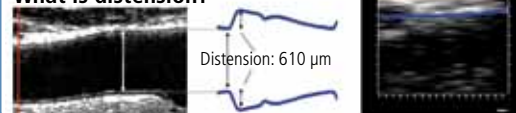
RFQAS targets the measurement of the blood vessel stiffness of a subject in a selected area of investigation. The blood vessel wall stiffness is expressed as pulse wave velocity obtained from brachial blood pressure and the accurate measurements of diameter and change in diameter. Moreover, the local blood pressure at the site of the ultrasound measurement is given.

Local blood pressure and stiffness is derived as quantification results based on sophisticated clinical studies.

### What is diameter?



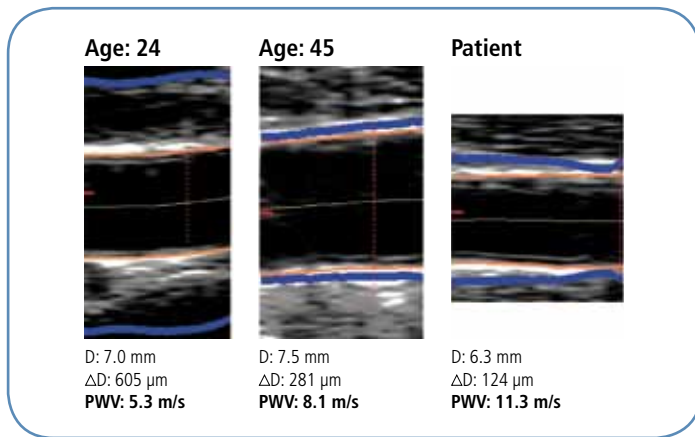
### What is distension?



Vessel parameters  
Diameter: 7.04 mm  
Distension: 610 µm  
Stiffness PWV: 5.7 m/s

## Stiffness measurements

During the scanning of the carotid artery the doctor gets real-time feedback on measurement quality via quality indicators overlaid on the ultrasound image at the position of the vessel wall (orange lines) and an indication of distension (green lines). This real time feedback gives the doctor the possibility to optimize his probe position to have the best perpendicular position of the scan plane in respect to the far wall of the common carotid artery.



Pictures of the set-up of the in-vitro testing system at the Eindhoven University of Technology

## <sup>RF</sup>QAS and <sup>RF</sup>QIMT Measurement Accuracy

The accuracy of both <sup>RF</sup>QAS and <sup>RF</sup>QIMT is extraordinary and superior compared to other currently available conventional technologies. The in-vitro verification has been carried out in co-operation with the Eindhoven University of Technology (TU/e).

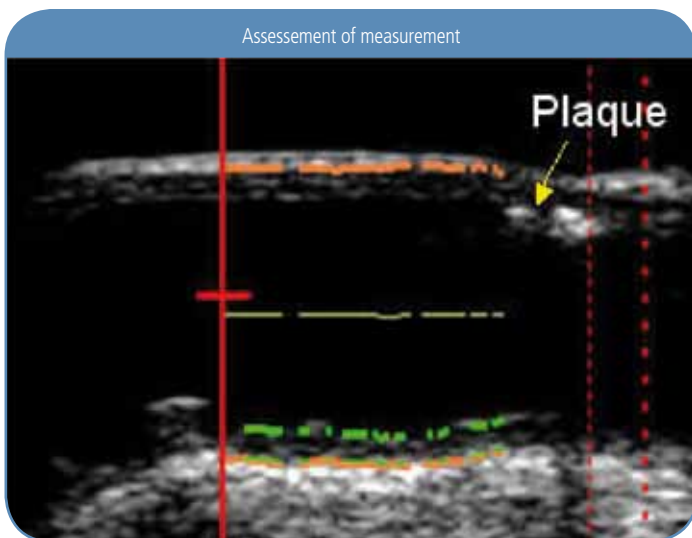
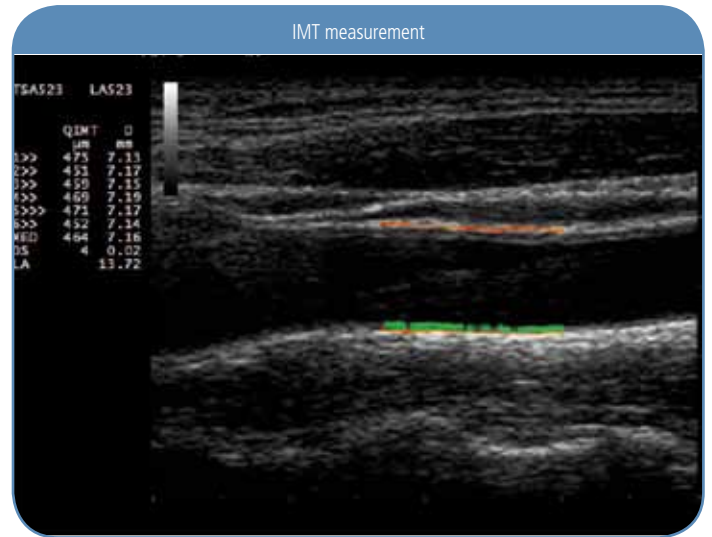
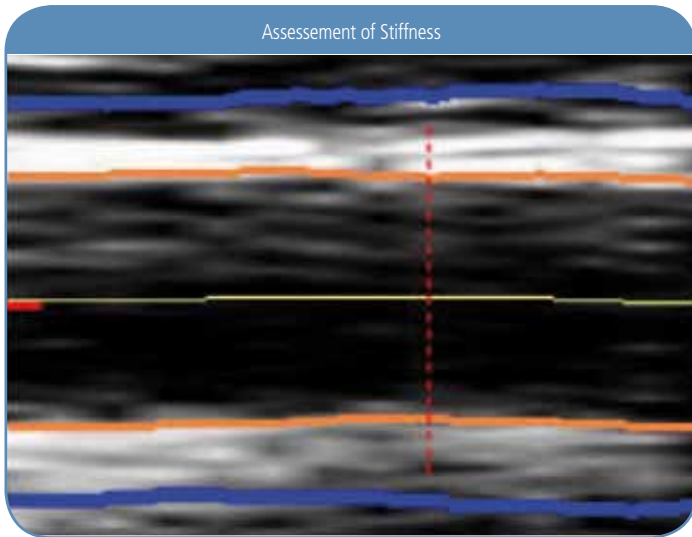
The maximum achievable accuracy as obtained in the in-vitro experiment is for diameter 51 μm, for distension 1,4 μm and for IMT 17 μm. The latter is valid also in presence of substantial difference in operator skill level.

The results of the in-vivo validation are reported in the following table. In order to realize these results; the system provides on-line feedback of the measurement by means of quality indicators overlaid on the ultrasound and via the Standard Deviation (SD) over 6 consecutive cardiac cycles.

In-vivo validation			
Intersession variability 3 weeks			
	Diameter (μm)	Distension (μm)	IMT (μm)
<sup>RF</sup> QIMT			21 (5%)
<sup>RF</sup> QAS	88 (1%)	31 (6%)	
Subjects: 12 Healthy volunteers			
Sex: 6 Male, 6 Female			
Age: between 23 and 56			

## Conclusion

The RF-data technology innovation as developed by Esaote makes it possible to measure automatically and accurately the positions of the anterior and posterior blood vessel wall, providing blood vessel wall diameter, change in diameter and blood vessel wall thickness of an artery as a continuous function of time. These measured basic blood vessel wall properties provide, by calculation, access to all major CVD related vascular stiffness parameters, e.g. pulse wave velocity.



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*Publication:* Journal of the American Heart Association

*Author:* Hélène Beaussier, Ingrid Masson, Cédric Collin, Erwan Bozec, Brigitte Laloux, David Calvet, Mustapha Zidi, Pierre Boutouyrie and Stéphane Laurent  
*Date:* September, 2008

**Title: Local arterial wave speed at carotid artery level is partly representative of carotid-femoral pulse wave velocity and aortic stiffness: evidence by a new echotracking technique**

*Publication:* 18<sup>th</sup> European Meeting on Hypertension

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*Date:* June 2008

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*Publication:* Journal of Biomechanics

*Author:* Ingrid Masson Pierre Boutouyrie, Stéphane Laurent, Jay D. Humphrey Mustapha Zidi  
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*Publication:* JN EPHROL

*Author:* Stéphane Laurent, Pierre Boutouyrie  
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*Publication:* Elsevier

*Author:* Evelien Hermeling, Koen D. Reesink, Robert S. Reneman and Arnold P.G. Hoeks  
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*Publication:* Journal of the American Heart Association

*Author:* Anna Paini, Pierre Boutouyrie, David Calvet, Anne-Isabelle Tropeano, Brigitte Laloux and Stéphane Laurent  
*Date:* January 2006

**Title: Clinical Application of Noninvasive Vascular Ultrasound in Cardiovascular Risk Stratification: A Report from the American Society of Echocardiography and the Society of Vascular Medicine and Biology**

*Publication:* Journal of the American Society of Echocardiography

*Author:* Mary J. Roman, MD, Tasneem Z. Naqvi, MD, FASE, Julius M. Gardin, MD, FASE, Marie Gerhard-Herman, MD, Michael Jaff, DO, and Emile Mohler, MD  
*Date:* August, 2006

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*Publication:* Cerebrovascular Diseases – Consensus paper

*Author:* P.-J. Touboul, M.G. Hennerici, S. Meairs, H. Adams, P. Amarenco, N. Bornstein L. Csiba, M. Desvarieux, S. Ebrahim, M. Fatar, R. Hernandez Hernandez, M. Jaff, S. Kownator, P. Prati, T. Rundek, M. Sitzer, U. Schminke, J.-C. Tardif, A. Taylor, E. Vicaud, K.S. Woo, F. Zannad, M. Zureik  
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*Publication:* European Heart Journal

*Author:* Stéphane Laurent, John Cockcroft, Luc Van Bortel, Pierre Boutouyrie, Cristina Giannattasio, Daniel Hayoz, Bruno Pannier, Charalambos Vlachopoulos, Ian Wilkinson, and Harry Struijker-Boudier on behalf of the European Network for Non-invasive Investigation of Large Arteries  
*Date:* 2006

**Title: Longitudinal studies reporting the independent predictive value of arterial stiffness:**

*Publication:* European Heart Journal (2006) 27, 2588–2605

First author (year, country)	Events	Follow-up (years)	Type of patient (number)	Mean age at entry (years)
Blacher (1999, Fr)	CV mortality	6.0	ESRD (241)	51
Laurent (2001, Fr)	CV mortality	9.3	Hypertension (1980)	50
Meaume (2001, Fr)	CV mortality	2.5	Elderly (>70) (141)	87
Shoji (2001, Jp)	CV mortality	5.2	ESRD (265)	55
Boutouyrie (2002, Fr)	CHD events	5.7	Hypertension (1045)	51
Cruickshank (2002, GB)	All cause mortality	10.7	IGT (571)	51
Laurent (2003, Fr)	Fatal strokes	7.9	Hypertension (1715)	51
Sutton-Tyrrell (2005, USA)	CV mortality and events	4.6	Elderly (2488)	74
Shokawa (2005, Jp)	CV mortality	10	General population (492)	64
Willum-Hansen (2006, Dk)	CV mortality	9.4	General population (1678)	55
Mattace-Raso (2006, Nl)	CV mt, CHD	4.1	Elderly (2835)	72
Stefanadis (2000, Gr)	Recurrent acute CHD	3	Acute CHD (54)	55
Blacher (1999, Fr)	All cause mortality	2.1	ESRD (79)	58
Barenbrock (2001, Ge)	CV events	7.9	ESRD (68)	43

**Title: Increased Carotid Wall Stress in Vascular Ehlers-Danlos Syndrome**

*Publication:* Journal of the American Heart Association

*Author:* Pierre Boutouyrie, Dominique P. Germain, Jean-Noël Flessinger, Brigitte Laloux, Jérôme Perdu and Stéphane Laurent  
*Date:* March, 2004

**Esaote S.p.A.**

International Activities: Via di Caciolle 15 - 50127 Florence, Italy - Tel. +39 055 4229 1 - Fax +39 055 4229 208 - international.sales@esaote.com - www.esaote.com  
Domestic Activities: Via A. Siffredi, 58 16153 Genoa, Italy, Tel. +39 010 6547 1, Fax +39 010 6547 275, info@esaote.com

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